

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in this application.

Listing of Claims:

Claims 1 – 60. Cancelled.

Claims 61 – 88 cancelled.

89 (New). Pantoprazole multiparticulates having reduced release under gastric conditions and fast release at neutral pH, wherein each of said multiparticulates comprises:

a spheroid core consisting of about 20 % w/w to about 45% w/w of a pantoprazole salt or a hydrate thereof and one or more excipients comprising about 25% to about 30% w/w microcrystalline cellulose, about 4% to about 6% w/w polysorbate 80, about 14% to about 16% w/w croscopolvidone, about 0.5 to about 2% w/w hydroxypropyl methylcellulose, about 5% to about 8% w/w sodium carbonate, and about 1 to about 2 % w/w water;

an initial seal coat comprising hydroxypropylmethyl cellulose on the spheroid core; and

an enteric coat on the initial seal coat,

wherein said multiparticulates have an average diameter of about 0.7 mm to about 1.25 mm.

90 (New). The multiparticulates according to claim 89, wherein the pantoprazole salt or hydrate thereof is selected from pantoprazole sodium, pantoprazole magnesium, or a hydrate thereof.

91 (New). The multiparticulates according to claim 89, wherein the hydrate is a sesquihydrate.

92 (New). The multiparticulates according to claim 89, wherein the pantoprazole salt or hydrate thereof is present in an amount of about 45% w/w.

93 (New). The multiparticulates according to claim 89, wherein said multiparticulates have an average diameter of about 1 mm.

94 (New). The multiparticulates according to claim 89, wherein said enteric coat comprises about 48% w/w of the particulate.

95 (New). The multiparticulates according to claim 89, further comprising a final seal coat on the enteric coat.

96 (New). The multiparticulates according to claim 95, wherein the final seal coat comprises about 0.1 to 10 wt% of the multiparticulates.

97 (New). The multiparticulates according to claim 95, wherein the final seal coat comprises hydroxypropyl methylcellulose (hypromellose).

98 (New). The multiparticulates according to claim 89, wherein said initial seal coat is in the range of about 2 to about 4 % w/w of the weight of the uncoated core.

99 (New). The multiparticulates according to claim 89, wherein the enteric coating comprises about 30% w/w of methacrylic acid and methacrylate copolymer, about 15% w/w talc, about 3% triethyl citrate and a pH adjuster; said amounts being by weight of the multiparticulates.

100 (New). Pantoprazole multiparticulates having reduced release under gastric conditions and fast release at neutral pH, wherein each of said multiparticulates comprises:

a spheroid core consisting of a pantoprazole salt or a hydrate thereof in an amount of about 40% w/w free pantoprazole and one or more excipients comprising about 25% to about 30% w/w microcrystalline cellulose, about 4% to about 6% w/w polysorbate 80, about 14% to about 16% w/w crospovidone, about 0.5 to about 2% w/w hydroxypropyl methylcellulose, about 5% to about 8% w/w sodium carbonate, and about 1 to about 2 % w/w water;

an initial seal coat comprising hydroxypropylmethyl cellulose on the spheroid core; and

an enteric coat on the initial seal coat,

wherein said multiparticulates have an average diameter of about 0.7 mm to about 1.25 mm.

101 (New). A product comprising a plurality of pantoprazole multiparticulates, each comprising a spheroid core consisting of a pantoprazole salt or a hydrate thereof in an amount of about 40% w/w free pantoprazole and one or more excipients comprising about 25% to about 30% w/w microcrystalline cellulose, about 4% to about 6% w/w polysorbate 80, about 14% to about 16% w/w crospovidone, about 0.5 to about 2% w/w hydroxypropyl methylcellulose, about 5% to about 8% w/w sodium carbonate, and about 1 to about 2 % w/w water;

an initial seal coat comprising hydroxypropylmethyl cellulose on the spheroid core; and

an enteric coat on the initial seal coat,

wherein said multiparticulates have an average diameter of about 0.7 mm to about 1.25 mm.

102 (New). The product according to claim 101, comprising about 10 mg to about 100 mg pantoprazole, based upon the weight of free pantoprazole base.

103 (New). The product according to claim 102, comprising about 40 mg pantoprazole, based upon the weight of free pantoprazole base.

104 (New). The product according to claim 102, wherein said plurality of multiparticulates are in an aqueous suspension.

105 (New). The product according to claim 102, wherein said plurality of multiparticulates are in a capsule.

106 (New). A method of producing a multiparticulate formulation of pantoprazole having reduced release under gastric conditions and fast release at neutral pH, said method comprising:

producing a spheroid core consisting of a pantoprazole salt or a hydrate thereof in an amount of about 40% w/w free pantoprazole and one or more excipients comprising about 25% to about 30% w/w microcrystalline cellulose, about 4% to about 6% w/w polysorbate 80, about 14% to about 16% w/w crospovidone, about 0.5 to about 2% w/w hydroxypropyl methylcellulose, about 5% to about 8% w/w sodium carbonate, and about 1 to about 2 % w/w water, via extrusion and spheronization;

applying an initial seal coat comprising hydropropyl methyl cellulose to the spheroid core;

applying an enteric coating to the initial seal coated spheroid core, said enteric coating comprising a copolymer of methacrylic acid and methacrylates; and

optionally applying a final seal coat to the enteric-coated spheroid core, said final seal coat being about 1 wt% of the multiparticulate;

wherein the multiparticulates have an average diameter of about 0.7 mm to about 1.25 mm.

107 (New). The method according to claim 106, wherein the spheroid core is prepared by mixing the ingredients in a low shear mixer at low shear conditions at a range of about 25 rpm to 35 rpm.

108 (New). The method according to claim 107, wherein the low shear conditions are 32 rpm.

109 (New). The method according to claim 106, wherein the spheroid cores are dried at a low temperature not exceeding about 40°C for a period of 8 to 72 hours to a percent (%) loss-on-drying (LOD) of 3.4% to 4.3%.

110 (New). The method according to claim 106, further comprising the step of applying a layer of talc in an amount of 0.05% w/w to 0.1% w/w of the multiparticulates.

111 (New). The method according to claim 106, wherein the enteric coating is sprayed as a suspension onto the spheroid core.

112 (New). A method of treating ulcers of the stomach and duodenum, gastroesophageal reflux disease (GERD), or Zollinger-Ellison Syndrome in a mammalian subject, comprising the step of administering to the subject a plurality of pantoprazole multiparticulates according to claim 89 comprising about 10 mg to about 100 mg pantoprazole, based upon the weight of free pantoprazole base.